K102165

Cachet Pharmaceuticals Pvt. Ltd.
Sterile Saline Solution
Premarket Submission 510 (K)

510(K) SUMMARY
FOR
Sterile Saline Solution

JAN 19 2011

This summary is provided in accordance with the Safe Medical Devices Act (SMDA) of 1990. The information provided in the 510 (K), Premarket Notification, was in accordance with 21 CFR 807.87

1. **Submitter of 510 (K)**

Cachet Pharmaceuticals Pvt. Ltd.
415 Shah Nahar, Worli
Mumbai 400 018
India

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2. **Product Code:**
LPN

3. **Device Name**
Classification Name: Soft (hydrophilic) Contact Lens Solution
Proprietary Name: Sterile Saline Solution

4. **Legally Marketed Predicate Devices**

Blairex Sterile Saline Solution – P850045

5. **Description of the Device**
Sterile Saline Solution is a sterile, preservative free, buffered, isotonic, clear, colourless aqueous solution containing Sodium Chloride, Sodium Borate, Boric Acid and Nitrogen as Propellant.

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The solution is packaged in lacquered aluminum spray containers with caps. Each container is sealed with a tamper evident hologram seal at the junction of the container and the cap.

6. **Indications for Use**
Sterile Saline Solution is indicated for rinsing and wetting of soft (hydrophilic) contact lenses.

7. **Description of Safety and Substantial Equivalence:**
A series of studies were completed to demonstrate the substantial equivalence of Sterile Saline Solution to the predicate device(s). All testing was conducted in accordance with and in conformance to applicable device regulations. Results demonstrate the solution is non-toxic and is comparable to other currently marketed soft contact lens solutions. Results from all tests demonstrate the substantial equivalence to previously approved predicate device(s).

Sterile Saline Solution is substantially equivalent in terms of its actions and indications for use Blairex Sterile Saline Solution – P850045 cleared for marketing under 510(K). Sterile Saline Solution meets the guideline set forth in FDA's May 1, 1997 Guidance for Industry, Premarket Notification 510 (K) Guidance Document for Contact Lens Care products.

Toxicity:
A series of cytotoxicity and eye irritation studies of the Sterile Solution were undertaken. In these studies, there was no evidence of toxicity

Bacteriostasis Test:
A bacteriostasis study was conducted in accordance with Micro Appendix C of the Premarket Notification 510 (K) Guidance Document for Contact Lens Care Products. The purpose of the study is to evaluate the ability of bacteria to survive in the reclosable containers containing Sterile Saline Solution (unpreserved borate buffered saline). The results show that Staphylococcus aureous, Escherichia coli, Pseudomonas aeruginosa, Candida albicans and Aspergillus niger have no significant growth and survive over the designed period. The data support the desire discard statement on label up to 30 days.

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8. **Substantial Equivalence**

The data provide in this 510(K) submission concludes that Sterile Saline Solution is substantially equivalent to currently cleared Blairex Sterile Saline Solution – P850045 cleared for marketing under 510(K) for rinsing and wetting of soft (hydrophilic) contact lenses.

SUBSTANTIAL EQUIVALENCE CHART

Substantial Equivalency	Sterile Saline Solution		Blairex Sterile Saline Solution P850045
Manufacturer	**Shegfried S.V.**		**Blairex Laboratories Inc.**
Intended Use (Indications for Use)	For rinsing and wetting of soft (hydrophilic) contact lenses		For rinsing, and wetting of soft (hydrophilic) contact lenses
Formulation	Sodium Chloride, Sodium borate Boric Acid . Purified Water		Sodium Chloride, Sodium borate, Boric Acid Purified Water
Propellant	Nitrogen		Nitrogen
Preservative	No		No
Sterility claim	Sterile		Sterile

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Cachet Pharmaceuticals Pvt. Ltd.
c/o Mr. Shivkumar Agrawal
415, Shah Nahar, Dr. E. Moses Road
Worli, Mumbai 400018
India

FEB - 9 2011

Re: K102165
Sterile Saline Solution
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (hydrophilic) contact lens care products
Regulatory Class: Class II
Product Code: LPN
Dated: January 19, 2011
Received: January 19, 2011

Dear Mr. Agwaral:

This letter corrects our substantially equivalent letter of January 19, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological, and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Sterile Saline Solution

Indications For Use:

Sterile saline is indicated for rinsing and wetting of soft (hydrophilic) contact lenses.

Prescription Use _____ AND/OR Over-The-Counter Use ✓
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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